

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 23-R-0018
CUSTOMER NUMBER: 303

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Wyeth Research Division
Of Wyeth Pharmaceuticals Inc
P.O. Box 8299
Philadelphia, PA 19101

Telephone: (215)-971-2610

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	146	574	128	118	820
5. Cats					
6. Guinea Pigs	5	164	185	10	359
7. Hamsters		239	793	25	1,057
8. Rabbits	67	634	125	8	767
9. Non-human Primate	162	799	112	34	945
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Ferrets					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

(b)(6), (b)(7)(c)

11/29/07

1192

Attachment to APHIS Form 7023
Column E Explanation for USDA Reporting Year
October 1, 2006 through September 30, 2007

Registration Number: 23-R-0018

(b)(2)High, (b)(7)f

Seventy-four (74) dogs were used in tests to assess the safety of new pharmaceuticals wherein unanticipated signs of gastrointestinal intolerability (emesis and or diarrhea) or one or more signs of organ system involvement (weight or body condition, cardiovascular signs, CNS signs, or anaphylaxis) were observed following dosing. All animals showing signs of pain or distress were attended by specially qualified veterinary staff; and any animals with severe or chronic signs of pain or distress were provided appropriate veterinary medical care. Safety assessment studies are required for the approval of human pharmaceuticals by international drug regulatory authorities and the FDA (Food, Drug and Cosmetics Act, CFR Title 21). Prior to the conduct of these studies, the IACUC determined that no alternatives were available and that the minimum numbers of animals of the appropriate species were used, consistent with obtaining valid results. The IACUC approved the withholding of treatment to insure that unexpected interactions of the treatment with the test compound or the masking of clinical signs required for safety assessment did not occur. Either would interfere with the interpretation of results and possibly invalidate the study. Invalid studies would need to be repeated, requiring the use of additional animals.

Thirty-four (34) nonhuman primates were used in tests to assess the safety of new pharmaceuticals wherein unanticipated signs of gastrointestinal intolerability, cardiovascular signs, and CNS signs were observed following dosing. All animals showing signs of pain or distress were attended by specially qualified veterinary staff; and any animals with severe or chronic signs of pain or distress were provided appropriate veterinary medical care. Safety assessment studies are required for the approval of human pharmaceuticals by international drug regulatory authorities and the FDA (Food, Drug and Cosmetics Act, CFR Title 21). Prior to the conduct of these studies, the IACUC determined that no alternatives were available and that the minimum numbers of animals of the appropriate species were used, consistent with obtaining valid results. The IACUC approved the withholding of treatment to insure that unexpected interactions of the treatment with the test compound or the masking of clinical signs required for safety assessment did not occur. Either would interfere with the interpretation of results and possibly invalidate the study. Invalid studies would need to be repeated, requiring the use of additional animals.

Eight (8) rabbits were used in tests to assess the safety of new pharmaceuticals wherein unanticipated signs of gastrointestinal intolerability (diarrhea) or one or more signs of organ system involvement (inappetence, ataxia, respiratory changes) were observed following dosing. All animals showing signs of pain or distress were attended by specially qualified veterinary staff; and any animals with severe or chronic signs of pain or distress were provided appropriate veterinary medical care. Safety assessment studies are required for

the approval of human pharmaceuticals by international drug regulatory authorities and the FDA (Food, Drug and Cosmetics Act, CFR Title 21). Prior to the conduct of these studies, the IACUC determined that no alternatives were available and that the minimum numbers of animals of the appropriate species were used, consistent with obtaining valid results. The IACUC approved the withholding of treatment to insure that unexpected interactions of the treatment with the test compound or the masking of clinical signs required for safety assessment did not occur. Either would interfere with the interpretation of results and possibly invalidate the study. Invalid studies would need to be repeated, requiring the use of additional animals.

(b)(2)High, (b)(7)f

Six (6) dogs were used in tests to evaluate the effects of test compounds in a pacing-induced model of heart failure wherein the dogs reach a level of compensated heart failure. All animals showing signs of pain or distress were attended by specially qualified veterinary staff; and any animals with severe or chronic signs of pain or distress were provided appropriate veterinary medical care. Heart failure is a necessary requirement for this model in order to test compounds for efficacy prior to human clinical studies. The experimental compounds tested are designed to alleviate or reduce the heart failure induced in this model. Prior to the conduct of these studies, the IACUC determined that no alternatives were available and that the minimum numbers of animals of the appropriate species were used, consistent with obtaining valid results. The IACUC approved the withholding of treatment to insure that unexpected interactions of the treatment with the test compound or the masking of clinical signs required for safety assessment did not occur. Either would interfere with the interpretation of results and possibly invalidate the study. Invalid studies would need to be repeated, requiring the use of additional animals.

Thirty-eight (38) dogs were used in tests to evaluate the efficacy of antiarrhythmic compounds in an aseptic pericarditis model of atrial fibrillation wherein arrhythmia is produced. All animals showing signs of pain or distress were attended by specially qualified veterinary staff; and any animals with severe or chronic signs of pain or distress were provided appropriate veterinary medical care. Test compounds are evaluated for their ability to eliminate or attenuate the atrial fibrillation that is induced in this model. Prior to the conduct of these studies, the IACUC determined that no alternatives were available and that the minimum numbers of animals of the appropriate species were used, consistent with obtaining valid results. The IACUC approved the withholding of treatment to insure that unexpected interactions of the treatment with the test compound or the masking of clinical signs required for safety assessment did not occur. Either would interfere with the interpretation of results and possibly invalidate the study. Invalid studies would need to be repeated, requiring the use of additional animals.

(b)(2)High, (b)(7)f

Twenty-five (25) hamsters were used in tests to assess the safety of new pharmaceuticals wherein unanticipated signs of one or more signs of organ system involvement (body condition, respiratory distress, cardiovascular signs, or CNS signs) were observed following dosing. All animals showing signs of pain or distress were attended by specially qualified veterinary staff; and any animals with severe or chronic signs of pain or distress were provided appropriate veterinary medical care. Safety assessment studies are required for the approval of human pharmaceuticals by international drug regulatory authorities and the FDA (Food, Drug and Cosmetics Act, CFR Title 21). Prior to the conduct of these studies, the IACUC determined that no alternatives were available and that the minimum numbers of animals of the appropriate species were used, consistent with obtaining valid results. The IACUC approved the withholding of treatment to insure that unexpected interactions of the treatment with the test compound or the masking of clinical signs required for safety assessment did not occur. Either would interfere with the interpretation of results and possibly invalidate the study. Invalid studies would need to be repeated, requiring the use of additional animals.

(b)(2)High, (b)(7)f

Ten (10) guinea pigs were used in tests to assess the efficacy of novel antigens with different adjuvants, including Complete Freund's Adjuvant (CFA) wherein signs of irritation (inflammation, distress, etc.) were observed following dosing. All animals showing signs of pain or distress were attended by specially qualified veterinary staff; and any animals with severe or chronic signs of pain or distress were provided appropriate veterinary medical care. Prior to the conduct of these studies, the IACUC determined that no alternatives were available and that the minimum numbers of animals of the appropriate species were used, consistent with obtaining valid results. The IACUC approved the withholding of treatment to ensure that the masking of clinical signs required to determine efficacy did not occur. Masking would interfere with the interpretation of results and possibly invalidate the study. Invalid studies would need to be repeated, requiring the use of additional animals.

Attachment to APHIS Form 7023
IACUC-Approved Exceptions for USDA Reporting Year
October 1, 2006 through September 30, 2007

Registration Number: 23-R-0018

(b)(2)High, (b)(7)f

Thirty-four (34) nonhuman primates were exempted from the provisions of 9 CFR§3.81 and the relevant facility Nonhuman Primate Environmental Enrichment Plan. Animals dosed with test compound for tolerability studies were required to be singly housed two to five days, depending on the study objectives. While the cages met the minimum housing requirements as defined in 9 CFR§3.6, they did not permit full conformance with the facility's Nonhuman Primate Environmental Enrichment Plan. The exemption is contained in the IACUC-approved animal protocols.

(b)(2)High, (b)(7)f

Eleven (11) dogs were exempted from the provisions of 9 CFR§3.8 and the relevant facility Canine Exercise Plan. Animals dosed with radio-labeled test compound are required to be housed in special metabolism cages. While the metabolism cages meet the minimum housing requirements for dogs as defined in 9 CFR§3.6, they do not provide sufficient space to comply with exercise requirements. The exemption is contained in the IACUC-approved animal protocol, and the attending veterinarian or their designee documents each occurrence in the animal's clinical record.